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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,014	12/04/2001	Chen Xing Su	10209.276	6898
21999 7590 05/07/2009 KIRTON AND MCCONKIE 60 EAST SOUTH TEMPLE, SUITE 1800 SALT LAKE CITY, UT 84111			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/07/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/006,014

Applicant(s)

SU ET AL.

Examiner

D L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10, 12, and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12, and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGEMENTS

1. The Examiner acknowledges receipt of the amendment filed 3/4/09 wherein claims 2, 11, and 14 are canceled. In addition, the Examiner acknowledges the request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/09 has been entered.

Note: Claims 1, 3-10, 12, and 13 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 3/4/09 to the rejection of claims 1, 3-10, 12, and 13 made by the Examiner under 35 USC 112 have been fully considered and deemed non-persuasive for the reasons of record in the office action mailed 12/9/08 and those set forth below.

112 First Paragraph Rejections (Written Description)

The rejection of claims 1, 3-10, 12, and 13 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 12/9/08 and those set forth below.

In summary, Applicant asserts that while the Examiner states that the terms 'inhibit' and 'inhibition' are not described in the specification, the terms are commonly used in the art to indicate interference with a chemical action or suppression of another substance (i.e., an enzyme). Applicant attached a copy of a search of books that

include in their text the terms 'inhibit' and 'inhibition'. Furthermore, Applicant asserts that one armed with the knowledge of a skilled artisan would understand what the unexpected effect of the claimed concentration of *Morinda citrifolia* juice.

Applicant's arguments are not persuasive for reasons for record in the office action mailed 12/9/08 and those below. The issue is not whether or not the prior art uses the term 'inhibit' or 'inhibition', but at a specific concentration, what, if any, amount of inhibition occurs. As an illustration, the Merriam-Webster dictionary defines the term 'inhibit' as 'a verb meaning to prohibit from doing something; to hold in check; and restrain' (the term 'inhibition' is the noun of the term 'inhibit'). Likewise, the term 'prohibit' as defined by Merriam-Webster's dictionary is defined as 'to forbid; to preclude; or to prevent from doing something'. Thus, based on the dictionary definitions, the interpretation of the terms could be complete inhibition or partial inhibition. Now, at the specific concentration percentage of 2.31 set forth in the independent claims, the biochemical assay in Example 1 (specification) discloses that at a concentration of 2.31 percent, inhibition of the COX-1 was 20% while inhibition of the COX-2 was almost 60 percent. Hence, two things are known, (1) the definitions of 'inhibition' and 'inhibit' in the art do not set any boundaries for the instant invention when a specific amount of *Morinda citrifolia* juice is administered. In other words, how the prior art may define 'inhibit' or 'inhibition' in a specific document is not necessarily consistent with that of the instant invention. (2) The presence of a specific concentration of *Morinda citrifolia* juice (2.31 concentration percentage), according to Example 1 of the specification, results in specific inhibition of both COX-1 and COX-2,

not some undetermined amount of inhibition as set forth in the pending claims (the instant claims only disclose a desired concentration percentage, not the concentration percentage in combination with the specific COX-1 and COX-2 inhibition values). Thus, the rejection is deemed proper.

112 First Paragraph Rejections (New Matter)

The rejection of claims 1, 3-10, 12, and 13 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 12/9/08 and those set forth below.

It is duly noted that Applicant did not respond to the new matter rejection. However, it should be noted that the rejection is being maintained for reasons of record in the office action mailed 12/9/08 and because while the pending claims read on Administering a specific concentration percentage of Morinda citrifolia juice, the specification discloses that at that specific concentration percentage, you obtain a specific amount of inhibition of COX-1 and COX-2. However, the pending claims read on any amount of inhibition of COX-1 and COX-2. Thus, the rejection is deemed proper.

112 First Paragraph Rejections (Scope of Enablement)

The rejection of claims 1, 3-10, 12, and 13 under 35 USC 112, first paragraph, because the specification, while being enable for COX-1 inhibition by 20% and COX-2 inhibition by 58% when a concentration of 2.31% of Morinda citrifolia juice is administered to a subject, does not reasonably provide enablement for complete inhibition or any other inhibition of COX-1 and/or COX-2, other than COX-1 inhibition by

20% and COX-2 inhibition by 58%, when a concentration of 2.31% of *Morinda citrifolia* juice is administered is MAINTAINED for reasons of record in the office action mailed 12/9/08 and those set forth below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In summary, Applicant asserts that the claims are enabled since they have been narrowed to recite a species of the formulation which is directly supported by the originally filed specification. In addition, Applicant asserts that the specification discloses working examples at both 2.31 and 10 concentration percentages. Furthermore, Applicant asserts that the specification indicates multiple ways of making the processed *Morinda citrifolia* product of claim 1.

The rejection is maintained for reasons of record in the office action mailed 12/9/08. Likewise, the arguments are non-persuasive for the reasons below. First, while Applicant discloses that the specification has working examples at both 2.31 and 10 concentration percentages, all of the independent claims are directed to 2.31 concentration percentage. Furthermore, what the specification discloses is that at a concentration of 2.31 percent, a certain amount of inhibition of both COX-1 and COX-2 occurs, not that the concentration percentage of 2.31 results in a range or varying amounts of inhibition based on the formed administered. As a result, that particular concentration percentage (2.31) results in a specific inhibition of COX-1 relative to COX-2. Secondly, the making of processed *Morinda citrifolia* in multiple ways is not the issue. (1) One issue is what is the relative amount of undesired COX-1 inhibition to

COX-2 when 2.31 concentration percentage *Morinda citrifolia* is administered?

Example 1 (specification) discloses the amount of COX-1 relative to COX-2 at that specific concentration percentage.

According to *In re Fisher*, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), an “inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law. However, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.” (emphasis added). Thus, based on the evidence of record, the rejection is deemed proper.

112 Second Paragraph Rejections

The rejection of claims 1, 3-10, 12, and 13 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 12/9/08 and those set forth below.

It is duly noted that Applicant did not respond to the 112, second paragraph, rejections. However, the rejection is maintained for reasons of record in the office action mailed 12/9/08 and those below.

Claims 1 and 5: In independent claim 1, it is set forth that the processed Morinda citrifolia is a juice. In claim 5, it is disclosed that Morinda citrifolia is in capsule form. A capsule form is not a juice. Also, in paragraph [0017] of the published application (US 2002/0090406), it is disclosed that Morinda citrifolia is generally administered in the form of a juice, oil, capsule, or as an ingredient in another food product. Thus, providing evidence that Applicant is not stating that a capsule is a juice. So, the two forms are distinct and claim 5 does not limit the juice form in independent claim 1.

Claims 1 and 8: Claim 8 is ambiguous because it is unclear what 'another food product' Applicant is referring to. What other food type is present in the claim(s)?

Claims 1 and 6: Claim 6 is ambiguous because it is unclear what COX-2 related prostaglandins that cause pain and inflammation are inhibited and what COX-1 related prostaglandins are inhibited to a lesser extent.

Claims 1 and 7: Claim 7 is ambiguous because independent claim 1 discloses a specific predetermined concentration percentage of Morinda citrifolia that is administered to a subject while claim 7 is directed to simply administering a predetermined concentration. In other words, if independent claim 1 is directed to a specific predetermined concentration amount, then what amount is claim 7 referring to?

Claims 1, 3-10, 12, and 13: The claims as written are ambiguous because in the independent claims, it is unclear what is the undesired COX-1 inhibition relative to COX-2 inhibition that Applicant is referring to. In other words, is Applicant referring to a total or partial inhibition and what is the value and conditions that determine whether or not the method is a success? Since the dependent claims depend on the independent claims, like the independent claims, the dependent claims are also vague and indefinite.

NEW GROUNDS OF REJECTIONS

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because independent claim 1 contains multiple periods (see the beginning and end of line 5). Thus, it is unclear whether there is text missing or not. Furthermore, each claim should begin with a capitalized letter and end with a period. As a result, only a single period should appear in the claim. Since, independent claim 1 is ambiguous, all claims depending thereupon (claims 3-8) are also vague and indefinite.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

May 4, 2009